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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/981,665	11/05/1997	STAN CIPKOWSKI	3000	8326

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EXAMINER

GRUN, JAMES LESLIE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/20/2005

LG

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/981,665

Applicant(s)

CIPKOWSKI, STAN

Examiner

James L. Grun

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 16-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

Pursuant to the Vacatur and Remand by the Board of Patent Appeals and Interferences on 31 March 2003, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a complete new brief in compliance with 37 CFR 41.37.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The disclosure is objected to because of the following informalities: page 4, line 18, --card-- is misspelled; page 11, line 11, --ply-- is misspelled. Appropriate correction is required.

Claims 16 and 19 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over May et al. (WO 88/08534) in view of Sun et al. (US 5,238,652).

May et al. (WO 88/08534) teach a variety of embodiments of an analytical test device. The device comprises a dry porous carrier, preferably a nitrocellulose membrane in the form of a strip (e.g., pages 5-6), having a labelled reagent, freely mobile in the carrier in the moist state, in a first zone located upstream from a detection zone on the carrier, the detection zone having unlabelled specific binding reagent for analyte immobilized therein (e.g., pages 3 and 7). Such test strip devices are for use in, for example, sandwich or competition immunoassays (pages 4-5 and 16-17) for detection of analytes such as drugs, infectious disease agents, pregnancy/fertility hormones, etc., in aqueous samples such as in a urine sample (e.g., pages 7-8, 17, and 20). With the choice of appropriate specific binding reagents, the general applicability of the test strip device is taught (e.g., page 17). Downstream from the detection zone a control zone may be present having, for example, an immobilized anti-mouse immunoglobulin antibody if the mobile labelled specific binding reagent is one derived from a mouse hybridoma (page 9). The porous carrier may be linked to a porous (e.g. bibulous) receiving member to which liquid sample can be applied, e.g. by dipping into sample contained in a vessel (pages 20 or 29), placement into flowing sample (page 24), or by means of a syringe (page 28), and from which the sample can permeate into the porous carrier (e.g., pages 6 and 8-9). The porous carrier may be further linked to a porous pad downstream from the assay zone(s) that serves as a sink for liquid passed through the carrier (e.g., pages 11 or 15, Fig. 1). The dry porous carrier can be "backed" or sandwiched with, for example, one or more plastic sheet(s) to increase its handling strength (e.g., pages 13-14) and/or provide a transparent seal against ingress of moisture or sample (e.g., pages 23 or 27). The test strip can be enclosed in a casing having apertures, holes, or windows for sample application and result and control observation, the shape of the apertures, holes, or

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windows not being critical (e.g., pages 7-8, 20, 27, or 28). If desired the observation apertures can be provided with transparent inserts (e.g., page 25). In some embodiments the test device can be sandwiched between upper and lower halves of the casing having a flat rectangular shape (e.g., pages 20, 24, or 27, Figs. 3 or 11). In embodiments wherein paper or other similar cellulosic materials are used as the porous receiving member, the reference implies that they are not sufficiently robust when wet to protrude from the casing (e.g., pages 9 or 21, Figs. 3, 7, or 13). A device according to the invention can incorporate two or more separate test strips, each having different reagents thereon to determine a plurality of analytes simultaneously, arranged in parallel in a single device (e.g., page 12). The reference contemplated that combinations and subcombinations of the features of the variously described and depicted test strips and casings formed part of the invention (page 40). In contrast to the invention as instantly disclosed and claimed, May et al. do not specifically teach the immunoassay means for determination of drugs of abuse as instantly disclosed and claimed.

Sun et al. teach membrane strips for competitive immunoassay of drugs of abuse (e.g. columns 5-6) and that the strips for such drug of abuse analytes may be configured in a parallel arrangement for simultaneous testing of multiple analytes (e.g. Fig. 3), at least five analytes in a single device being preferred (e.g. column 2). The reference teaches that the strips can be constructed for alternative competitive immunoassay formats (see e.g. column 10) wherein either: antigen in sample and antigen immobilized on the membrane support compete for binding with mobile latex-labelled antibodies; or, mobile latex-labelled antigen and antigen in the sample compete for binding with antibodies immobilized on the membrane support.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have constructed the test strips in the device of May et al. with reagents in a competitive immunoassay format for determination of drugs of abuse wherein antigen in sample and antigen immobilized on the test strip compete for binding with mobile latex-labelled antibodies because May et al. teach the general applicability of their devices for determinations of analytes such as drugs with selection of appropriate binding reagents and Sun et al. teach that such constructions were well known alternatives in the art for determinations of drugs of abuse on immunoassay test strips. It would have been further obvious to one of ordinary skill in the art at the time the instant invention was made to have provided the test strips of May et al. in view of Sun et al. in any alternative casing/holder comprising combinations of features taught by May et al., such as a strip as depicted in Fig. 1 of the reference in a casing as depicted in Fig. 11, because May et al. teach that such combinations are possible and because one would have had ample motivation to select from the alternative casing/holder features taught by the reference with the expectation that such would perform the desired casing/holder function. One would have been motivated to provide a casing such as that depicted in Fig. 11 for a nitrocellulose test strip as depicted in Fig. 1 in view of the teachings in May et al. that the sample receiving portion thereof was not sufficiently robust to protrude from a casing. It would have been further obvious to have arranged a plurality of test strips for different drugs of abuse in parallel in a single device in May et al., as modified, because May et al. teach such arrangements for the simultaneous determination of a plurality of analytes and Sun et al. teach that test strips, which may be configured in a parallel arrangement, for the determination of at least five drug of abuse analytes in a single device is preferred.

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Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Claims 16-19 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over May et al. (WO 88/08534) in view of Sun et al. (US 5,238,652) as applied to claims 16 and 19 above, and further in view of Boger et al. (US 4,518,565).

The teachings of May et al. in view of Sun et al. are as set forth above and differ from the invention as instantly disclosed or claimed in not teaching specific means for the parallel arrangement of a plurality of test strips in a single casing as desired.

Boger et al. (US Pat. No. 4,518,565) teach a rigid holder for holding multiple dip-and-read reagent test devices such as the test strips illustrated in the figures. Such reagent devices can be dipped into a biological sample, such as urine, to provide a detectable response, such as a color change, as a quantitative or at least semiquantitative indication of a constituent or component in the test sample (see e.g. col. 1). Reagent devices usable in the holder of Boger et al. include those dip-and-read test devices for conducting immunochemical tests (e.g. col. 2, lines 58-62). The holder is provided having a base member and a top member which permit multiple individual test devices to be positioned parallel to one another. The base member can have ridges or other means which facilitate the preferred precise parallel alignment of the reagent test devices in the holder (e.g. col. 3, lines 63-66). The top member has openings, exposing each reagent area on the test devices for the application of specimen or sample and the taking of measurements, which can be any configuration, but are preferably the same configuration as the reagent pads on the reagent devices (e.g. ¶¶ bridging cols. 2-3 and 3-4). The holder of the

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invention is applicable for multiple reagent devices having either multiple (e.g. Figs. 1-2) or single reagent pads (Fig. 3 and cols. 3-4). Although a single opening 22 for each "single pad" device is set forth in the text, two openings for each of these reagent devices are clearly depicted for this embodiment of the holder (Fig. 3). The holder can be constructed of any suitable material, including various copolymers, plastics, metal, or coated cardboard (see e.g. col. 3, lines 50-62). The top and bottom members may be provided separately, becoming engaged in a suitable fashion after placement of the test devices thereon or therein, or as a foldable assembly (cols. 3-4). Although other configurations such as a circular holder with test devices radiating out from the center are possible, the preferred rectangular shape of the holder, as depicted in the figures, permits the maximum number of test devices to be inserted into a holder of the smallest possible dimensions (col. 4, lines 24-33). The devices may extend beyond the holder (see Figs.) or the holder can be made long enough to accommodate the test devices in their entirety (col. 4, lines 54-58). The holders may be either disposable or reusable and may be used for storage of test devices after their use for testing (col. 4, lines 14-23, and col. 5, lines 50-53). The entire holder can be dipped into the sample to be tested, or sample can be applied to the reagent pads of the devices in the holder by a convenient means which can be automated (& bridging col. 4-5). The holder of the invention has the advantages of convenience, simplicity, relative inexpensiveness, positiveness, effectiveness, durability, accuracy, and directness of action (e.g. col. 5, lines 12-15). Thus the holder meets the stated objects of providing a rigid holder for multiple reagent test devices (col. 2, lines 51-53), for making simultaneous analyses of liquid fluid (e.g. claim 1) such as urine (col. 1, line 30), and for protecting the reagent pads prior to use (e.g. col. 5, lines 33-38). Implicit in the disclosure of the holder is that automated processing of

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the devices in the holder, although an additional object of the invention, is not required for the use of the holder because the holder is taught as usable with multiple conventional, low cost, test devices having a visual result rather than a more expensive alternative format (e.g. col. 5, lines 18-21). Boger et al. do not specifically teach strips for immunoassay of drugs of abuse.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have provided the test strips of May et al. in view of Sun et al. in a casing/holder of a design such as those taught by Boger et al., having ridges or other means which facilitate the preferred parallel alignment of the strips, because one would have had ample motivation to select from known and conventional alternative casing/holder components, such as the ridges defining slots to facilitate parallel test strip arrangement, with the expectation that such a known casing/holder design would perform its desired casing/holder and arrangement functions. It would have been obvious to have formed the ridges, defining parallel slots, in the base member for strip alignment, as taught in Boger et al., in May et al., as modified, by any conventional means because one of ordinary skill would have expected a conventional means such as lamination or gluing of multiple layers, molding, or cutting, to form the desired ridges and slots therein for the desired parallel alignment. One would have had ample motivation to have selected from among such conventional known techniques with an expectation of success. Further, it would have been an obvious matter of design choice to have provided closed slots in the embodiment of the holder taught in the reference of Boger et al. for use with the test strips of May et al. as modified wherein the test devices are accommodated in their entirety in order to ensure not only parallel alignment of the devices but also proper alignment of the openings in the top member with the reagent area(s) on each of the test devices for the application of specimen

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or sample and the taking of measurements. Alternatively, it would have been an obvious matter of design choice to have adhered the test strips to the casing/holder device of May et al., as modified, because a disposable casing/holder was contemplated, and May et al. teach (e.g., page 23) that the strips are to be held firmly in place, as is conventional in the art, to prevent shifting of the test strips in the casing/holder device and facilitate proper alignment of the openings in the top member with the reagent area(s) on each of the test devices for the application of specimen or sample and the taking of measurements.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Appellant's arguments filed previously have been fully considered but they are not deemed to be persuasive in view of the NEW GROUNDS of rejection set forth herein.

In response to appellant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Arguments against individual aspects of the references which were not relied upon in the rejection and which do not serve to teach away from the invention as a whole, such as particular structural elements of various particular embodiments of the housings/holders of Sun et al. or of the test strips of Boger et al., were not found persuasive. For example, appellant urges that Sun et al teach an embodiment wherein sample flows through a passage of a device housing before coming in contact with the lateral flow immunoassay test strip therein. This is not found persuasive as the reference teaches other embodiments in which an absorbent pad is found at the sample application opening of the

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housing and the test membrane, having the colored latex spheres sensitized or coated with detecting antibodies impregnated thereon in close proximity to the opening and the absorbent pad, is implicitly in close proximity to or in contact with the opening and absorbent pad. There is no disclosure in appellant's specification regarding whether the instant test strip does or does not include an absorbent pad at the sample receiving portion. The reference of Sun et al is cited for its specific disclosure of membrane strips containing reagents for competitive immunoassay of drugs of abuse, i.e. the "immunoassay means" on the immunoassay test strips disclosed by appellant's specification, and not for the particularities of the housings chosen by the reference for the test strips. May et al. clearly teach apertures in casings registering with sample receiving portions of test strips therein. Appellant urges that Boger et al. do not teach lateral flow immunoassay test strips. This is not found persuasive in view of the teachings of May et al. and Sun et al. The reference of Boger et al. is cited for its teachings regarding means which facilitate the preferred precise parallel alignment of reagent test strips in a holder.

Appellant urges that Boger et al. only teach a test strip holder wherein the "handle" of a test strip therein extends from the top of the holder. This is not found persuasive in view of the cited reference teachings that the holder can be made long enough to accommodate the strips in their entirety (column 4). Appellant's assertion that removal of the test strips for measurement is required by Boger et al. was not found persuasive because the reference clearly teaches a holder in which openings are provided for sample application and for taking assay measurements in a photometric apparatus, if desired, on the multiple test strips preloaded in the holder. Moreover, the holder may be disposable and/or used for long term storage after use in testing, embodiments which would clearly be inconsistent with appellant's arguments. Moreover, May

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et al. teach detection of visual signal on an immunological test strip detection zone on a test strip contained in a casing.

Appellant urges that the housings/holders of Sun et al. or of Boger et al. do not teach paired openings to expose sample and test portions of a test strip to the atmosphere. This is not found persuasive in view of the teachings of May et al. wherein apertures for sample application and reading the results in the detection zone are clearly taught. There is no requirement in the instant disclosure that both sample and test portions of a test strip are exposed to the atmosphere as would appear appellant's argument. The sample application portion needs to be accessible for sample application through an opening or aperture, but it would seem a matter of design choice, as taught in May et al., whether one covers the detection zone aperture with a transparent seal or insert to provide additional protection against ingress of moisture or sample. Indeed, appellant uses the terms openings and windows interchangeably in the disclosure (pages 12-13) and there is no specific teaching in the instant specification regarding whether the instant test strips do or do not include the conventional backing or sandwiching with plastic taught in May et al.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,372,515 B1.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent drawn to a test card having test strips exposed on both front and rear surfaces makes obvious a test card as instantly claimed having test strips exposed on either surface. Moreover, the reference teaches that the test strips can be on one or both sides of the test card.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

May et al. (US 5,602,040) contains an essentially identical disclosure as found in May et al. (WO 88/08534).

Huang et al. (US 5,712,172) teach sandwiching, by lamination, of an immunochromatographic device between a backing material and a plastic covering material to obviate the need for a plastic housing. The covering material partially covers the device or encompasses one or more openings or holes to provide an exposed sample receiving region (e.g. Figs. 1 and 4) and, if not of a clear material, an additional window, gap, or hole is provided in the covering for results viewing (e.g. col. 7, lines 23-31). Illicit drugs are suggested analytes for detection with the invention (see e.g. column 4). The reference does not teach the sample

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receiving portion of the device spaced from the bottom end of the device. The reference also does not specifically teach housing multiple devices for a number of analytes in a single assembly.

Davis (US 5,119,830) teaches an analytical specimen cup having a chemical test “strip” with a plurality of “pads” for multiple analytes, in one embodiment the strip being the size and shape of a card (see e.g. Figure 6) having the multiple analyte pads arranged in parallel.

Lee-Own et al. (US 5,500,375) disclose laminated immunochromatographic devices for detection of analytes, including drugs of abuse (e.g. columns 5 or 8). Immunochromatographic assay means, such as impregnated nylon membrane strip(s) (e.g. column 5), are laminated between sealing means and support means, such as adhesive films or plastic sheets (columns 7-9). The reference teaches transparent plastic for the sealing/support means, thereby exposing the membrane strip(s) for viewing as the reference teaches that observation of the result through a test window is required of such devices (see e.g. col. 1, lines 55-65). Lamination would be expected to provide a slot-like “recess” in the films and/or sheets housing the strip(s) as depicted in any of Figs. 2, 3, 9, or 11. Multiple membrane strips may be configured in a single device to allow for multiple assays (e.g. column 7, lines 21-23). The device may be incorporated into a sample collection vessel such as a urine collection vessel (e.g. column 8). In use, the end of the membrane strip(s) is/are exposed by cutting the laminate or peeling off a protective cover and the membrane(s) contacted with sample by dipping into, immersion into, or application thereto of sample.

Galloway et al. (US 5,403,551) teach (see e.g. Figs. 1-5) a plurality of chromatographic strips (five are shown, but a greater or smaller number of strips may be used (column 4)) for

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analyzing a sample, such as drug-specific immunoassay chromatographic strips for analyzing a urine sample (columns 3-4), disposed in a generally parallel relationship on a cover, comprising a thin flat rectangular member of a size permitting insertion into the depicted collection container, along a longitudinal axis of the sample collection container. Ribs may be provided for positioning and separation of the strips in what would appear to be slots (see e.g. Fig. 4).

Friedman et al. (US 4,055,394) disclose a diagnostic test card.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



James L. Grun, Ph.D.
May 15, 2005



LONG V. LE
SUPERVISORY PATENT EXAMINER
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05/17/05